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EXAMINER

QM22/0226

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ART UNIT | PAPER NUMBER
3739 | 18

DATE MAILED: 02/26/01

☑ This application has been examined ☑ Responsive to communication filed on November 15, 2000 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1,4-6,11-21,53-60 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 2,3,7-10,22-52,61-69 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☑ Claims 1,4-6,11-21,53-60 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 11, and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, it is unclear what further method steps are to be inferred from the structure claimed therein. In claim 11, "the loose skin surface" "lacks positive antecedent basis. In claim 14 it is unclear what further method step is intended to be recited given the definition of "reverse thermal gradient" in the sentence spanning pages 5 and 6 of the ordinally filed specification. In claim 15-18 "heating a loose skin surface overlying a collagen continuing tissue site" lacks positive antecedent basis.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21, 55, and 56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. The specification does not enablingly disclose how to control the temperature or how to enablingly sense the temperature of the underlying tissue.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5, 11-21 and 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sand ('709) in combination with Storm, III. Sand ('709) teaches a method of contracting collagenous tissue by controlled heating with a reverse thermal gradient and notes the presence of collagen throughout the body including skin and muscle. Storm III teaches heating tissue using RF and microwave energy and a reverse thermal gradient, as well as controlling the temperature at the various levels of tissue, measuring the temperatures and measuring the impedance of the tissue. It would have been obvious to the artisan of ordinary skill to employ the method of Sand ('709) to remove wrinkles, since this is a well known condition remedied by cosmetic surgery and to employ the heating method of Storm, III to provide the heat to shrink the tissue, since this can controllably heat tissue beneath the skin surface, as taught by Storm III, and to contract subdermal, deep dermal, or subcutaneous tissue, since these would all result in tightening of the skin which would in turn reduce the wrinkle; it would be similarly obvious to treat a wrinkle in the face, since the face is common site for cosmetic surgery including wrinkle

removal; to use ultrasound as the energy, since this is equivalent to rediofrequency energy and microwaves, and since ultrasound energy is notorious for its ability to heat tissue, official notice of which is hereby taken, thus producing a method such as claimed.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sand ('709) in combination with Storm, III as applied to claims 1, 4, 5, 11-21 and 53-60 above, and further in view of Lax et al ('242). Lax et al ('242) teach applying an electrolytic media to the surface of the tissue to be heated. It would have been obvious to the artisan of ordinary skill to apply an electrolytic media to the surface of the tissue ot be treated, since this provides a more even thermal gradient in the tissue, as taught by Lax et al ('2452), thus producing a method such as claimed.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

David Shay:bhw
February 22, 2001

DAVID M. SHAY
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GROUP 330